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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,109	02/25/2004	Masaaki Goto	16991.017	1642
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ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206			EXAMINER PAK, MICHAEL D	
			ART UNIT 1646	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/785,109

Applicant(s)

GOTO ET AL

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-35 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 32-35 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National-Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Amendment filed October 26, 2007 has been entered.
2. Applicant's arguments filed October 26, 2007, have been fully considered but they are not found persuasive.
3. Claims 1-31 have been canceled and claims 32-35 have been added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 32 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "OCIF protein", which is indefinite. There is no structure associated with this term and there is no art accepted meaning of this term at the time

the instant invention was filed. Therefore, the metes and bounds of what is to be encompassed by this term are unclear and the claims are indefinite.

Applicants argue that one skilled in the art would understand that the OCIF protein refers to a "...compound that is produced by human lung fibroblast cells and inhibits osteoclast differentiation and/or maturation having a molecular weight of about 60 kD and about 120 kD under non-reducing conditions and about 60 kD under reducing conditions on SDS-polyacrylamide gel electrophoresis. However, terms are relative and can change from scientific paper to another. Furthermore, the term does not define the specific structure of the amino acid sequence.

Applicants argue that the specification discloses the OCIF purification. However, the specification cannot be imported into the claims and the claim limitation "OCIF" is not defined by the specification. Furthermore, the term "OCIF" is not merely large in breadth but has no structural definition.

5. Claims 32 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass a polypeptide variants of SEQ ID NO:5 without structural limitations because of the recitation of the polypeptide by name only. However, the essential feature of the invention is not clear because the polypeptide SEQ ID NO:5

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structure is not provided, and one of skilled in the art cannot envision the full genus of molecules of the claimed polypeptide molecules. The claims encompass variants whose structure is not known or other variant proteins with different function from SEQ ID NO:5 taught in the specification. Claimed protein variants encompass a large genus of proteins which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

Applicants argue that written description can be fulfilled by disclosing an adequate number of species. However, all the description is of only one species and the genus is claimed by name only without structural limitation.

It is suggested that percent identity language with functional language be used in the claim limitation drawn to SEQ ID NO:5 if supported by the specification.

6. Claims 32 and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an osteoclastogenesis inhibitory factor protein comprising an amino acid sequence SEQ ID NO:5, does not reasonably provide enablement for an osteoclastogenesis inhibitory factor protein is limited by name only. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of § 112 requires that the patent specification enable "those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." Genentech, Inc. v. Novo Nordisk AIS, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)); see also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Likewise, in Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), the court affirmed the holding of invalidity of claims to analogs of the EPO gene under § 112 for lack of enablement where applicants had claimed every possible analog of the EPO gene but had disclosed only how to make EPO and a very few analogs. "[D]espite extensive statements in the specification

concerning all analogs of the EPO gene that can be made, there is little enabling disclosure of the particular analogs and how to make them There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them." *Id.*, 927 F.2d at 1213-14, 18 USPQ2d at 1027.

Claims encompass variants with unlimited changes to SEQ ID NO:5 because of the claim to protein limited by name only. However, one skilled in the art cannot make and to use variants of SEQ ID NO:5. The state of the art is such that one skilled in the art prior to the time of the invention did not know how to create unlimited number of variants of SEQ ID NO:5 which are functional. The amount of direction provided in the specification is limited to a specific species of SEQ ID NO:5. One skilled in the art would require empirical experimentation in order to determine the changes to SEQ ID NO:5 sequence without disrupting the structure of the receptor activity. However, the specification does not teach how to use variants of SEQ ID NO:5 which are functional. Proteins have active sites which are essential for the proper function of the protein in its interaction with the polynucleotide or polypeptide domains (McKenna et al., *Endocrine Review* 1999). A fragment of the binding protein which is truncated in the middle of the various domains or a fragment which does not allow the proper folding of the domain or is deleted would not be expected to function. The state of the art is such that one skilled in the art cannot predict the outcome of changes to protein structure using the primary amino acid structure as the predictor (Bowie et al., *Science*, 1989). Thus, one skilled in the art cannot use the primary amino acid sequence of SEQ ID NO:5

polypeptide alone to predict the tertiary structure of SEQ ID NO:1 polypeptide which would be required to determine the protein function and proper folding of SEQ ID NO:5 polypeptide. No working example is provided to determine whether a change in the domains of SEQ ID NO:5 polypeptide variant would provide proper function. It would require empirical experimentation to determine whether the variants of SEQ ID NO:5 is functional. Thus, variants encompass a genus with a large number of species which are not functional. In view of the extent and the unpredictability of the experimentation required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation. Therefore, based on the above Wands analysis, a preponderance of the evidence supports a conclusion that one skilled in the art would not have been enabled to make and use the claimed invention without undue experimentation.

Applicants argue that new claim limitations recite the molecular weight of OCIF and thus is a limiting genus. However, the specification does not enable the unlimited changes to SEQ ID NO:5 such that it has no similarity to the original species of SEQ ID NO:5 isolated. Applicants argue that one skilled in the art would recognize which positions of the OCIF protein are amenable to mutations and conservative substitutions. However, one skilled in the art at the time of the invention did not have the structure-function analysis of SEQ ID NO:5 to recognize the changes which are relevant to creating functional mutant much less a large genus of mutant variants or a protein which has not similarity in structure to SEQ ID NO:5.

Applicants argue that in addition to purifying and isolating the OCIF protein, applicants have characterized numerous functional, chemical and physical properties. However, the characterization of the specific species of SEQ ID NO:5 was not in the unlimited changes to SEQ ID NO:5 to claim a large genus of OCIF. No characterization of the structure – function relationship has been established to enable one skilled in the art to make changes and maintain function.

Applicants argue that OCIF 2-5 have been isolated and have function. However, the OCIF are fragments of SEQ ID NO:5 which was isolated in the hybridization process. It is well known to one skilled in the art that the cDNA library are composed of different fragments of the cDNA transcribed from the RNA prior to packaging in the library. The specification does not provide one skilled in the art how to isolate a functional OCIF which is completely different in structure from the claimed species of SEQ ID NO:5 in the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 32-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable claims 1-2 of prior U.S. Patent No. 6,855,808. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-2 of U.S. Patent No. 6,855,808 anticipates the claims 32-35 of the present application. The polypeptide of claims 1-2 of prior U.S. Patent No. 6,855,808 inherently has the functional claim limitation. Applicants argue that there is an embodiment of the invention that falls within the scope of one claim but not the other. Since the claims are anticipated by one species over the generic claim, both sets of claims are encompassed within the genus.

Applicant argue that they are willing to consider submitting a terminal disclaimer in the present case with regard to '808 patent upon indication of allowable subject matter. Until a terminal disclaimer is filed or other appropriate action is taken, the rejection will be maintained.

8. Claims 32-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable claims 1-14 of prior U.S. Patent No. 7,125,686.

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Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-14 of U.S. Patent No. 7,125,686 comprises the same protein as the polypeptide of claims 32-35 of the present application. The polypeptide of claims 1-14 of prior U.S. Patent No. 7,125,686 inherently has the same function. Applicants argue that there is an embodiment of the invention that falls within the scope of one claim but not the other. Since the claims are anticipated by one species over the generic claim, both sets of claims are encompassed within the genus.

Applicant argue that they are willing to consider submitting a terminal disclaimer in the present case with regard to '808 patent upon indication of allowable subject matter. Until a terminal disclaimer is filed or other appropriate action is taken, the rejection will be maintained.

9. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Pak
Primary Examiner
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